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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,118	10/30/2001	Stanford Mark Moran	INT 004.10	8022

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1646	

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11/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/004,118	MORAN, STANFORD MARK	
	Examiner	Art Unit	
	JEGATHEESAN SEHARASEYON	1646	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *87,88,90-96 and 98-114* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *87,88,90-96 and 98-114* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/1/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/03/2010 has been entered. An action on the RCE follows.

2. Claims 87, 88, 90-96 and 98-114 are pending and examined.

Information Disclosure Statement

3. The IDS submitted on 5/1/2009 has been considered.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4a. The rejection of Claims 87, 88, 90-96 and 98-108 and 114 under 35 U.S.C. 103(a) as being unpatentable over Goeddel et al. (U. S. Patent No. 5, 120, 832) in view of Parker et al., (WO 00/40273– cited in the IDS received on 5/31/2007) and Albrecht *et al.* (U. S Patent No. 6, 172, 046) further in view of Theeuwes et al. (U.S. Patent No. 4, 976, 966) is maintained for reasons set forth in the Office Action dated 2/3/09.

The claims of the instant invention are drawn to a method of treating hepatitis C virus (HCV) infection in a subject in need thereof, comprising administering a therapeutically effective amount of omega IFN to the subject. The claims are further drawn to administering various dosage ranges of omega IFN, various routes of administration, and administration of omega IFN via a device such as an implanted pump.

Goeddel *et al* teaches an interferon, termed "leukocyte interferon", or IFN-$_{II}$1, which the instant specification discloses to be omega IFN (paragraph 0053 of instant specification). Goeddel *et al* teaches that this IFN possess biological activities similar or overlapping with other type I IFNs, including antiviral activity (column 2, line 67 – column 3, line 4; column 7, line 50 – column 8, line 19), and is suitable for therapeutic applications for treatment of viral infections and malignant and immunosuppressed or immunodeficient conditions (column 3, lines 15-19). However, Goeddel *et al* does not specifically teach administration of omega IFN for treatment of HCV infection.

Parker *et al* teaches treatment of viral diseases by administering an omega IFN-expressing polynucleotide (see page 5, lines 12-21), and specifically HCV (page 3, lines 24-25; page 23, lines 14-28; Example 6). The reference demonstrates that administration of an omega IFN-expressing polynucleotide is capable of increasing serum omega IFN levels in a subject, and that this increased serum omega IFN can be beneficial in the treatment of HCV. Furthermore, Parker *et al* teaches treatment of HCV by administration of an omega IFN-expression polynucleotide (see claims 1 and 29). Parker *et al* is silent regarding administration of omega IFN protein or use of any device for administration.

Albrecht *et al*. teach the administration of various amounts of interferon-α to treat HCV (abstract). The reference discloses that approximately 20-250 micrograms/kilogram per week on a weekly basis (column 3, lines 38-40).

Albrecht *et al.* also disclose various routes of administration (column 4, lines 35-49).

Theeuwes *et al* discloses an implantable, osmotic pump suitable for long-term administration of various drugs (abstract, column 2, line 53 – column 4, line 14), but is silent regarding a method of treatment of HCV by administration of omega IFN, or use of an implantable, osmotic pump in said method.

One of ordinary skill in the art, at the time the instant invention was conceived, would have been motivated to practice the method of the instant invention by following the combined teachings of Goeddel *et al*,, Parker *et al.*, Albrecht *et al.,* .and Theeuwes *et al.* Specifically, Goeddel *et al*, by teaching that omega IFN protein possesses type I IFN biological activity, including antiviral activity, provides motivation to use omega IFN, and also provides the skilled artisan with the knowledge of a specific omega IFN polypeptide. In addition, the disclosure of Parker *et al*, by teaching that HCV infection can be treated by omega IFN expressed in a subject by administration of a polynucleotide encoding omega IFN, provides the motivation to treat HCV by administration of omega IFN protein. Albercht *et al.* teach the administration of interferon-α (a Type I interferon like omega IFN) with specific dosage regiments to treat HCV.

Furthermore, because Parker *et al* suggests that therapeutic, systemic levels of omega IFN are beneficial for treatment of viral infections such as HCV (page 24, lines 23-38), one of ordinary skill in the art would be motivated to practice a method of omega IFN administration that results in sustained levels of omega IFN. Theeuwes *et al*, by teaching an implantable osmotic pump capable

of long-term delivery of pharmaceutical agents, provides a device capable of sustained delivery of omega IFN. Therefore, the combined teachings of Goeddel *et al*, Parker *et al*, Albercht *et al,* and Theeuwes *et al* provides a person of ordinary skill in the art with the motivation to treat HCV infection by sustained administration of the omega IFN protein of Goeddel *et al*, in the dosages suggested by Albercht *et al* via the implantable osmotic pump of Theeuwes *et al.*

In the instant case, the general conditions of the claims, administration of omega IFN for treatment of HCV infection, are obvious in view of the combination of Goeddel *et al*, Parker *et al*, Albercht *et al,* and Theeuwes *et al*, and therefore it would be obvious to optimize conditions such as dosage and timing and route of administration.

With respect to Applicant's arguments and declaration filed 10/29/08 has been fully considered but are not found to be persuasive. Applicant is asserting that none of the references teaches a method of treating HCV in a subject comprising administering a therapeutically effective amount of omega interferon protein to the subject. They are also arguing that the office is suggesting gene therapy protocols to treat HCV based on Parker *et al.* reference because the reference teaches the administration of a polynucleotide encoding an omega interferon. Applicant is asserting that Office is making conclusionary statement with respect to the administration of omega IFN protein administration. Applicant is arguing that there is no evidence provided to indicate that there would be a reasonable expectation of success when extrapolating form one treatment method (gene therapy) to a completely different treatment method (direct

administration of protein). In addition, Applicant is claiming that there is no *in vivo* treatment disclosed in Parker *et al.* It is argued that the statement by the Office that the Parker reference demonstrates that administration of an omega IF expressing polynucleotide is capable of increasing serum omega IFN levels in a subject, and that this increased serum omega IFN can be beneficial in the treatment of HCV is an overstatement. It is also asserted that Parker *et al.* reference teaches away from the invention.

The declaration of Dr. Alessi discusses the limitation of gene therapy. Applicant is also asserting that Goeddel *et al.* does not teach a method of treating HCV in a subject comprising administering a therapeutically effective amount of omega interferon protein to the subject. It is further argued that Theeuwes *et al.* does not teach a method of treating HCV in a subject comprising administering a therapeutically effective amount of omega interferon protein to the subject. It is also asserted that none of the reference teach the administration of omega interferon. Further, the Applicant argues that the Office is incorrectly claiming that just because alpha interferon is used in the treatment of HCV, then one of ordinary skill in the art would with reasonable degree of predictability know that omega interferon would provide useful treatment of HCV. Applicant is also claiming unexpected results. Finally, Applicant based on the declaration and the arguments presented is claiming that the instant invention is not obvious over the prior art of record.

Applicant appears to be arguing the references individually. The Office relied on the combined teaching to show the obviousness of the instant invention.

It is noted that the courts have held that it is not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art, *In re Keller,* 642 F.2d 413, 288 USPQ 871 9ccpa 1981). In addition, the motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combine for their common known purpose. Section MPEP 2144.07. With reference to Applicant's assertion that the Office is suggesting or teaching gene therapy protocols by the use of Parker *et al.*, the Office relied on this reference to show that HCV can be treated by omega IFN administration The reference also taught that serum omega IFN levels in a subject can be increased, and that this increased serum omega IFN can be beneficial in the treatment of HCV (see page 24, lines 16-27). Parker reference teaches that intramuscular injection of omega IFN plasmid DNA result in systemic levels of the IFN protein (page 24, lines 24-25). While it is true that there is no *in vivo* data is presented by Parker *et al.*, there is no such requirement for data because the art often extrapolates the *in vitro* data. In addition, the Office is not FDA to require *in vivo* data. Contrary to Applicant's assertion that Parker *et al.* teaches away from the invention it does teach the administration omega IFN for the treatment of HCV. In addition, Goeddel *et al.* reference was used to teach the administration omega IFN protein to treat viral diseases. Further, the dosages and the frequency to be administered for the treatment of HCV are suggested by Albercht *et al.* While it is true that the

references teach the administration of alpha IFN for the treatment HCV, the references provided contemplate the use of omega IFN for the treatment of HCV. The prior art provided to suggest unexpected results by Applicant is not persuasive because prior to Buckwald et al. (2007) Parker et al. (2000) contemplated the use of omega IFN for the treatment viral diseases including HCV. Again contrary to Applicant's declaration indicating that omega IFN was not used to treat HCV prior to the instant invention (see page 15 of the response) is not persuasive because Parker et al (2000) clearly taught the use omega IFN for the treatment HCV. Thus, the administration of omega IFN for treatment of HCV infection, is obvious in view of the combination of Goeddel *et al*, Parker *et al*, Albercht *et al,* and Theeuwes *et al*, and therefore it would be obvious to optimize conditions such as dosage and timing and route of administration. Therefore the rejection of record is maintained.

4b. The rejection of Claims 86, 97, 103 and 109-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goeddel *et al* (US 5,120,832) in view of Parker *et al* (WO 00/40273 – cited in the IDS received on 5/31/2007),and Albrecht *et al.* (U. S Patent No. 6, 172, 046) further in view of Theeuwes *et al* (US 4,976,966) and Guillen *et al* (US 6,074,673) is maintained for reasons set forth in the Office Action dated 2/3/09.

The claims of the instant invention are drawn to a method of treating hepatitis C virus (HCV) infection in a subject in need thereof, comprising administering a therapeutically effective amount of omega IFN to the subject.

The claims are further drawn to administering various dosage ranges of omega IFN, various routes of administration, and administration of omega IFN via a device such as an implanted pump. The claims are also drawn to a kit comprising the device.

The teachings of Parker *et al*, Goeddel *et al.,* Albrecht *et al.*.and Theeuwes *et al*, have been disclosed above in paragraph 6a. However, these teachings do not disclose a kit with multiple implantable devices.

Guillen discloses kit with multiple implantable devices with different concentration of medication (column 3, lines 55-65). It also discloses slow release of the medicament (column 3, lines 55-65). The reference is silent regarding a method of treatment of HCV by administration of omega IFN, or use of an implantable, osmotic pump in said method.

It would have been *prima facie* obvious to the artisan of ordinary skill in the art to modify the methods disclosed in the Parker *et al*, Goeddel *et al*. Albrecht et al. and Theeuwes *et al* to also contain a kit disclosed in Guillen to contain multiple implants for the administration of interferon-omega to treat HCV. Then artisan would have been motivated to include a kit with multiple implantable devices to generate varied doses because this will allow the subject to maintain the desired levels of interferon-omega during extended periods for the treatment of HCV. There is a reasonable expectation of success because Guillen discloses use of these kits with multiple implantable devices for allergy desensitization. Therefore, claims 86, 97, 103 and 109-113 are rejected as being obvious over the combined teaching of Goeddel *et al* (US 5,120,832) in view of Parker *et al*

(WO 00/40273 – cited in the IDS received on 5/31/2007),and Albrecht *et al.* (U. S Patent No. 6, 172, 046) further in view of Theeuwes *et al* (US 4,976,966) and Guillen *et al* (US 6,074,673).

Applicant's arguments have been addresses above in paragraph 4a.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5a. Claims 87, 88, 90-96, 98-108 and 114 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 7, 727, 519 (Application No. 10/982,532). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention and that of '519 are

both directed to method of treating HCV by administering IFN-omega. The patient population that is treated in the instant invention will also encompass the patient population of '519 Application that is resistant ton alpha interferon. Therefore, claims 87, 88, 90-96, 98-108 and 114 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 1-22 as being unpatentable over claims 1-22 of U.S. Patent No. 7, 727, 519. (These claims were previously provisionally rejected)

Conclusion

6. No claims are allowable.

7. This is a RCE of applicant's earlier Application No. 10/004, 118. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEGATHEESAN SEHARASEYON whose telephone number is (571)272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph. D can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/
Primary Examiner, Art Unit 1647

JS
11/17/2010